Extraimmunization Among US Children

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Context Little is known about the extent of extraimmunization, ie, vaccine doses given in excess of the recommended schedule, and whether it should be a public health concern.

Objectives To determine the extent and cost of extraimmunization in children and to identify its associated factors.

Design, Setting, and Participants United States 1997 National Immunization Survey, in which telephone interviews were conducted with parents of 32 742 19- to 35-month-old children and vaccination histories were collected from health care providers for 22 806 of these children (overall response rate, 68.5%). Estimates were weighted to represent the full sample.

Main Outcome Measures Frequency of extraimmunization compared by vaccine type as well as with adequate immunization; factors associated with extraimmunization; and vaccine and visit costs associated with extraimmunization.

Results Frequency of extraimmunization was less than 5% for each vaccine considered except poliovirus (14.1%). Overall, 21% of children were extraimmunized for at least 1 vaccine vs 31% underimmunized for at least 1 vaccine. In a multivariate model, the strongest contributors to extraimmunization were having more than 1 immunization provider (odds ratio [OR], 2.8; 95% confidence interval [CI], 2.4-3.2) and having multiple types of providers (eg, private and public health department; OR, 2.0; 95% CI, 1.6-2.4). Children seen only in public health department clinics were significantly less likely to be extraimmunized (OR, 0.3; 95% CI, 0.2-0.3). Annual costs associated with extraimmunization for this cohort of children were estimated conservatively at $26.5 million.

Conclusions These data indicate that extraimmunization can be costly. The challenge is to reduce extraimmunization without interfering with more important efforts to combat underimmunization. Improvements in immunization record keeping and sharing practices may help reduce extraimmunization.

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ACHIEVING AND SUSTAINING high immunization rates among US children is an important public health goal that has been vigorously pursued in the last decade. Extensive research on the factors that contribute to underimmunization[1-3] has led to a variety of interventions, including provider education to assess practice coverage levels and to reduce missed opportunities,[4,5] mass media campaigns to educate parents about the importance of immunization,[6] and efforts to reduce financial and other barriers to immunization.[4] National immunization coverage levels are now higher than ever before.[7]

However, little attention has been paid to extraimmunization, ie, vaccine doses given in excess of the recommended schedule. One possible consequence of aggressive immunization interventions and the use of untargeted educational campaigns is the unintentional administration of extra vaccine doses. Other factors that may contribute to extraimmunization include suboptimal record-keeping practices and the enforcement of minimum ages and intervals for vaccine doses as a requirement for school entry.

When complete provider vaccine history records and the parent-held "shot card" are lacking at the time of a health care visit, the physician may be guided by recommendations to give age-appropriate immunizations.[8,9] Such action may result in the administration of extra, unneeded doses. Extra vaccine doses also may be required to "fix" earlier errors in vaccine spacing. If 2 vaccine doses are given too close together or if a vaccine dose is given earlier than the minimum age, the dose may be appropriately repeated. The extent of such errors has not been well documented, but a small study in 4 Los Angeles, Calif, public health clinics found that 22% of the children studied had received "inappropriately timed" immunizations by ages 25 to 36 months.[10]

Little is known about the effects of receiving extra vaccine doses. The Advisory Committee on Immunization Practices (ACIP) recommends that children not receive more than 6 doses each of diphtheria and tetanus toxoids before the age of 7 years because extra

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doses may cause adverse local or systemic effects.[11,12] No limits are recommended for other routine childhood vaccines because there is no similar evidence of harm from extra doses,[13] although it has been postulated that extra doses of some vaccines are more likely to induce hypersensitivity to vaccine components.[14] However, even if medically safe, extraimmunization is inefficient and unnecessarily costly, and thus, undesirable.[15]

A few small studies have examined the question of extraimmunization. A population-based study of 187 children born in Dallas, Tex, in 1986 and 1987 found that by age 72 months 18% had received 1 or more extra vaccine doses.[15] Another population-based study of 2048 children born in 1992 and 1993 and living in one Minnesota county found that 5% of the children had been given extra immunization doses by age 24 months.[16] These studies were conducted when the recommended immunization schedule was less complex.

This study sought to determine the extent and associated costs of extraimmunization among US children aged 19 to 35 months and to identify factors associated with extraimmunization in the population under study. The findings can be used to determine if extraimmunization should be a public health concern and, if so, to identify ways to prevent it.

METHODS

Study Population

We analyzed data from the 1997 National Immunization Survey (NIS), a representative survey of children aged 19 to 35 months. Information is collected continuously in 2 steps. First, a random-digit dialing sample of telephone numbers in each of the 50 states and in 28 selected urban areas is generated. Approximately 1.6 million telephone numbers are contacted annually to reach a targeted 440 age-eligible children in each study area, for a total target sample size of 34 320. A screening questionnaire is administered to adult respondents to identify households with 19- to 35-month-old children. In households with an eligible child, a parent is interviewed to collect demographic information, the child's immunization history, and consent to contact the child's immunization provider(s). In the second step, the child's immunization history is requested from the identified immunization provider(s). Where information is received from more than 1 provider for the same child, duplicate values are eliminated and a composite vaccination history is created. Only children for whom provider information was obtained were included in this analysis.

Adjustment weights are calculated for each child to adjust for households with multiple telephone numbers, household nonresponse, and lack of a telephone through poststratification using the National Health Interview Survey. Then, the sample is adjusted to reflect US Census Bureau population totals by race/ethnicity, mother's education, and age of the child. Finally, adjustments for infant mortality, immigration, and migration rates are conducted based on natality files from the National Center for Health Statistics.[17,18]

Definitions of Immunization

Adequate immunization was defined according to the 1995 ACIP recommended childhood immunization schedule, before the 1996 recommendation for varicella vaccine.[19-21] Intervals between doses were not considered; only the number of doses received was counted. Between birth and 18 months of age, 14 or 15 vaccine doses are recommended: 3 doses of hepatitis B vaccine, 4 doses of diphtheria and tetanus toxoids and pertussis vaccine (DTP/DTaP [acellular pertussis]), 3 or 4 doses of *Haemophilus influenzae* type b (Hib) vaccine, 3 doses of poliovirus vaccine, and 1 dose of measles-containing vaccine.[19] Extraimmunized children were those who received more than the number of recommended doses for any vaccine(s). Underimmunized children were those who received fewer than the number of recommended doses for any vaccine(s).

We first calculated the frequency of adequate immunization, extraimmunization, and underimmunization by vaccine type. Then we calculated the frequency of children who were adequately immunized, extraimmunized (without being underimmunized), underimmunized (without being extraimmunized), and the remainder (both extraimmunized and underimmunized). Children who were underimmunized for any vaccine were then removed from the sample.

Statistical Analysis

Further analyses compared only adequately immunized with extraimmunized children. First, we evaluated the frequency of available child, family, and provider characteristics in a bivariate analysis. Then, using the characteristics that were significantly different ($P<.05$) in the bivariate analysis, we modeled the association of being either extraimmunized or adequately immunized using logistic regression. Because we were seeking to build a descriptive model that simultaneously controlled for all variables rather than a "best fit" model, we included all of the significant variables from the bivariate analysis. The initial frequency calculations and bivariate analysis were conducted using SAS software, version 6.12 (SAS Institute, Cary, NC). The logistic regressions were conducted using SUDAAN, release 7.5.2 (Research Triangle Institute, Research Triangle Park, NC).

Cost Analysis

To estimate the cost of the extra vaccine doses administered, we generated a frequency distribution for each vaccine type, assigned a price from the 1997 Centers for Disease Control and Prevention vaccine price list (unpublished data, January 15, 1997), and calculated the total vaccine cost. We assumed that all extra vaccines administered in a public setting were purchased by public funds. The number of extra vaccines administered in other settings was weighted to achieve an overall distribution of 61% publicly and 39% privately

purchased vaccine doses, approximating the 1997 US funding distribution of vaccine doses (R. Snyder, Centers for Disease Control and Prevention, written communication, June 15, 1999). Since we were not able to determine particular vaccine brands or combination vaccines administered, we used prices for noncombination vaccines only. Where more than 1 product was available, we assumed the products were equally distributed and calculated average public and private prices. We priced the following vaccine products: hepatitis B, pediatric dosage (average of 2 brands); DTP/DTaP (average of 3 brands); Hib (average of 3 brands); inactivated poliovirus vaccine and oral poliovirus vaccine; and measles, mumps, and rubella vaccine. Where poliovirus vaccine type was unknown, we assumed that the oral formulation was administered.

It is estimated that for every 95 vaccine doses used, 5 doses are wasted.[22] We assumed an equal distribution of waste among vaccines. To calculate vaccine waste, we divided the total number of extra vaccine doses administered by 95% to determine the estimated number of extra purchased vaccine doses. We then subtracted the extra doses administered from the extra doses purchased and multiplied the result by the average cost per extra vaccine dose.

Finally, we estimated the number of extra visits made to receive extra vaccine doses. An extra visit was defined as a visit to a provider where only 1 or more extra vaccine doses were received and no recommended, "nonextra" doses were received. Using 1994 figures and a 5% discount rate, we calculated the combined average visit cost and the cost to administer a vaccine in 1997 as $11.58 for public clinics and $20.26 for private offices.[23] For visits to other provider types, we averaged the public and private visit costs.

RESULTS

In the 1997 NIS, information on 32 742 children was collected from parents (93.8% interview completion rate) and provider information was collected for 22 806 (70%) of these, for an overall response rate of 68.5% (TABLE 1). No differences were observed between children with and without provider data by sex or age; however, significant differences were noted between groups by

Table 1. Characteristics of All Children Sampled (N = 32 742), by Whether They Had Provider Data—United States, National Immunization Survey, 1997*

Characteristic	Provider Data (n = 22 806)		No Provider Data (n = 9936)		*P* Value
	Unweighted No.	Weighted %	Unweighted No.	Weighted %	
Sex					
Male	11 685	51	5143	52	.45
Female	11 121	49	4793	48	
Age, mo					
19-25	9532	42	4076	41	.21
26-35	13 274	58	5860	59	
Race					
White	17 428	77	6753	70	<.001
Black	3809	16	2399	22	
Other	1569	7	784	8	
Persons in household					
1-2	786	3	377	3	<.001
3-5	18 745	82	7741	78	
>5	3172	15	1690	18	
Unknown	103	<1	128	1	
Mother's education, y					
≤12	9993	54	4860	59	<.001
>12	12 813	46	5076	41	
Mother's marital status					
Married	17 049	74	6482	65	<.001
Separated/divorced/widowed	1930	9	938	9	
Never married	3786	17	2277	23	
Mother deceased	10	<1	19	<1	
Unknown	31	<1	220	3	
Family income, $					
≤10 000	2199	11	975	11	<.001
10 001-20 000	2998	14	1126	12	
20 001-50 000	8094	33	3094	28	
50 001-75 000	3494	15	1164	11	
>75 000	2672	11	898	8	
Unknown	3349	16	2679	30	
Parent-reported 4:3:1 immunization coverage†	14 661	62	5879	58	<.001

*Weighted values reflect percentages representative of population totals; unweighted values reflect raw sample sizes.
†Respondent reported during the interview that child was up to date with the 4:3:1 combined series of vaccines: 4 doses of diphtheria-tetanus-pertussis (or acellular pertussis) vaccine, 3 doses of poliovirus vaccine, and 1 dose of measles-containing vaccine.

Table 2. Weighted Percentage of Level of Vaccination by Vaccine—United States, National Immunization Survey, 1997*

Vaccine	Children, % (95% CI)		
	Extraimmunized	Adequately Immunized	Underimmunized
Hepatitis B	4.9 (4.5-5.3)	79.3 (78.5-80.1)	15.8 (15.1-16.5)
DTP/DTaP	3.4 (3.0-3.8)	78.8 (78.0-79.6)	17.8 (17.0-18.6)
Haemophilus influenzae type b	3.5 (3.1-3.9)	89.5 (88.9-90.1)	7.0 (6.5-7.5)
Poliovirus	14.1 (13.4-14.8)	77.0 (76.2-77.8)	8.9 (8.3-9.5)
Measles	2.5 (2.2-2.8)	88.4 (87.7-89.1)	9.1 (8.5-9.7)

*CI indicates confidence interval; DTP, diphtheria-tetanus-pertussis (DTaP includes acellular pertussis).

race, household size, mother's education, mother's marital status, household income, and parent-reported 4:3:1 immunization coverage (Table 1).

By vaccine, the frequency of extraimmunization was less than 5% for all vaccines except poliovirus, for which 14.1% of children were extraimmunized (TABLE 2). Overall, about half (53%) the children in this cohort were adequately immunized, 27% were underimmunized for at least 1 vaccine but were not extraimmunized for any vaccine, 17% were extraimmunized for at least 1 vaccine but were not underimmunized for any vaccine, and 4% were both underimmunized and extraimmunized for at least 1 vaccine. Therefore, 21% were extraimmunized for at least 1 vaccine.

In the bivariate analysis, extraimmunized children were more frequently male. Significant differences also were noted between adequately immunized and extraimmunized children by age, race/ethnicity, household income, geographic region, and provider facility type (TABLE 3). Children whose parents reported vaccination history from a shot card were more frequently extraimmunized, as were children with more than 1 immunization provider. The following family characteristics showed no significant differences: mother's age and education, number of children in the household, and birth order.

Results of the multivariate logistic model (TABLE 4) indicate that the available child, family, and provider characteristics explain approximately 11% of the variance between adequately immunized and extraimmunized children and that the model is significantly better than random ($\chi^2 = 1865.71$; $P<.001$). Hispanic or Asian/Pacific Islander race/ethnicity and older age (30-35 months) were the only child or family characteristics associated with extraimmunization that were statistically significant in the multivariate model. Children with more than 1 provider were almost 3 times more likely to be extraimmunized than children with only 1 provider (odds ratio [OR], 2.8; 95% confidence interval [CI], 2.4-3.2). Children who saw multiple types of providers (eg, health department and private) were twice as likely as those who saw only private providers to be extraimmunized (OR, 2.0; 95% CI, 1.6-2.4). Children immunized only in health department public clinics (OR, 0.3; 95% CI, 0.2-0.3) and only in hospitals (OR, 0.6; 95% CI, 0.5-0.9) were less likely to be extraimmunized.

The cost analysis found a total of 1.8 million extra vaccine doses administered

Table 3. Bivariate Analysis of Child, Family, and Provider Characteristics for Adequately Immunized and Extraimmunized Children—United States, National Immunization Survey, 1997*

Characteristic	Adequately Immunized (n = 12 102)		Extraimmunized (n = 3856)		*P* Value
	Unweighted No.	Weighted %	Unweighted No.	Weighted %	
Child Characteristics					
Sex					
Male	6140	50	1997	53	.04
Female	5962	50	1859	47	
Age, mo					
19-24	4233	35	1198	30	<.005
25-29	3644	30	1191	31	
30-35	4225	35	1467	39	
Race/ethnicity					
White	8383	66	2384	58	<.001
Hispanic	1447	16	634	21	
Black	1612	13	593	14	
Asian/Pacific Islander	379	3	153	5	
American Indian/Alaskan Native	166	1	52	1	
Other	115	1	40	1	
Family Characteristics					
Family income					
Below poverty level	1966	18	712	21	<.005
At or above poverty level to $50 000	4849	38	1552	37	
>$50 000	3572	29	1025	25	
Unknown	1715	15	567	17	
Family and Provider Characteristics					
Geographic region					
Northeast	2132	19	676	19	.04
Midwest	2916	23	815	21	
South	4321	36	1512	35	
West	2733	22	853	25	
Did parent have shot card?					
Yes	6777	56	2257	60	.006
No	5325	44	1599	40	
Provider Characteristics					
No. of providers					
1	9340	78	1890	48	<.001
>1	2762	22	1966	52	
Provider facility type					
Private only	6936	58	1989	54	<.001
Multiple types	694	5	842	22	
Health department only	2085	18	184	5	
Hospital only	695	6	164	4	
Community/migrant health center only	445	3	127	3	
Military/other only	261	2	71	1	
Unknown	986	8	479	12	

*Weighted values reflect percentages representative of population totals; unweighted values reflect raw sample sizes.

nationwide at an average cost of $9.90 per dose (TABLE 5). This represents an excess cost of approximately $18.2 million. In addition, an estimated 96 795 vaccine doses were wasted at a cost of almost $1 million and an extra 412 569 clinic/office visits were made to receive only extra vaccine doses, at a cost of $7.3 million. Annual costs associated with extraimmunization for this cohort of children were estimated conservatively at $26.5 million.

COMMENT

With about 1 in 5 (or 900 000 of 3.9 million) US children receiving at least 1 extra vaccine dose by age 19 to 35 months, extraimmunization is clearly widespread and consequently quite costly. The extent of extraimmunization identified in this study represents a national excess cost of at least $26.5 million for the 19- to 35-month-old population. This is a conservative estimate that does not consider the cost of vaccine storage, handling, and distribution; parents' travel time; loss of wages; treatment for adverse events (if any) associated with extraimmunization; or other indirect costs.

While we cannot expect extraimmunization to be eliminated completely because extra doses are sometimes necessary to ensure that a child is fully immunized, reducing the extent of extraimmunization is desirable. It is particularly important that extra doses of diphtheria and tetanus toxoids be avoided to prevent potential adverse events.

Understanding the factors that contribute to extraimmunization will be important in reducing its incidence. In our multivariate logistic regression model, individual and family characteristics offered little explanatory power. Instead, provider characteristics were most strongly associated with extraimmunization. In particular, children with more than 1 immunization provider were more likely to be extraimmunized. The likelihood of extraimmunization also varied by type of provider: whereas 56% of children seen by multiple provider types were extraimmunized, 8% of those seen only in health department clinics received extra vaccine doses.

Another study showed similar differences in extraimmunization rates by providers, ranging from 5% for most providers to 33% for children ever seen in a particular system of public clinics. The authors were able to determine that the records of the public clinic system in question often did not reflect prior immunizations received at that clinic or elsewhere.[15]

Lack of ready access to complete and accurate immunization records seems to be the likeliest explanation here as well. When children see new providers or are referred for immunizations outside their source of primary care, particularly if the providers are of different types (eg, public health department clinic vs private practice), their immunization records may not follow them. One solution is to use parent-held shot cards.[4]

Community- and state-based immunization registries[24] represent an alternative to relying on shot cards. These computer databases keep track of individuals' immunization histories and are accessible from providers' offices. In addition to facilitating record sharing between providers, immunization registries can help providers avoid vaccine spacing errors by determining when shots are due. Registries also are useful for implementing strategies shown to be effective at reducing underimmunization. They can be used to assess coverage levels in practices and to generate reminder and recall notices when immunizations are due or late.

While provider characteristics are important in explaining extraimmunization in this study, they, along with the individual and family characteristics that were significant in the bivariate analysis, explained only a small percentage of the variation between extraimmunized and adequately immunized children. Clearly, other factors must contribute to extraimmunization. Further research on immunization record-keeping practices across different provider types may offer some insight.

When examined by antigen, poliovirus vaccine is the largest contributor to extraimmunization. It is the only antigen for which the percentage of extraimmunized exceeds the percentage of underimmunized children. There are sev-

Table 4. Logistic Model of Child, Family, and Provider Characteristics That Predict Extraimmunization—United States, National Immunization Survey, 1997*

Characteristic	Weighted % Extra-immunized	Odds Ratio (95% CI)
Sex		
Male	25	Referent
Female	23	0.9 (0.8-1.0)
Age, mo		
19-24	22	Referent
25-29	25	1.2 (1.0-1.4)
30-35	26	1.3 (1.1-1.5)
Race/ethnicity		
White	22	Referent
Hispanic	30	1.5 (1.2-1.8)
Black	25	1.3 (1.0-1.5)
Asian/Pacific Islander	35	2.1 (1.5-2.8)
American Indian/ Alaskan Native	23	1.0 (0.6-1.5)
Other	21	0.8 (0.5-1.5)
Family income		
Below poverty level	27	Referent
At or above poverty level to $50 000	24	0.9 (0.8-1.1)
>$50 000	22	0.8 (0.7-1.0)
Unknown	26	1.1 (0.9-1.3)
Geographic region		
Northeast	25	Referent
Midwest	22	0.8 (0.7-1.0)
South	24	0.9 (0.7-1.0)
West	26	0.8 (0.7-1.0)
Did parent have shot card?		
Yes	25	Referent
No	22	1.0 (0.9-1.0)
No. of providers		
1	17	Referent
>1	42	2.8 (2.4-3.2)
Provider facility type		
Private only	23	Referent
Multiple types	56	2.0 (1.6-2.4)
Health department only	8	0.3 (0.2-0.3)
Hospital only	17	0.6 (0.5-0.9)
Community/ migrant health center only	20	0.7 (0.5-1.0)
Military/other only	18	0.6 (0.4-1.0)
Unknown	32	1.2 (1.0-1.4)

*CI indicates confidence interval.

Table 5. Direct Costs Associated With Extraimmunization—United States, National Immunization Survey, 1997*

Cost Item	Weighted No. of Extra Doses or Visits			Average Cost per Dose or Visit, $		
	Total	Public	Private	Public	Private	Total Cost, $
Extra vaccine doses administered						
Hepatitis B	330 932	216 622	114 310	8.17	17.59	3 780 515
DTP/DTaP	235 430	148 210	87 220	14.06	19.19	3 757 584
Hib	240 709	150 133	90 576	6.48	14.71	2 305 235
Poliovirus (oral)	866 815	508 069	358 746	2.32	10.47	4 934 791
Poliovirus (inactivated)	8374	5085	3289	5.49	14.96	77 120
MMR	156 847	99 038	57 809	16.31	30.00	3 349 580
Extra vaccine total	1 839 107	1 127 157	711 950	9.90		18 204 824
Vaccine waste	96 795	. . .	. . .	9.90		958 271
Extra clinic/office visits	412 569	117 732	294 837	11.58	20.26	7 336 734
Total Costs						**26 499 829**

*DTP indicates diphtheria-tetanus-pertussis (DTaP includes acellular pertussis); Hib, *Haemophilus influenzae* type b; MMR, measles-mumps-rubella; and ellipses, data not broken down by source.

eral possible explanations for this discrepancy. First, the recommended time frame for administering the third dose of polio vaccine spans a full year and overlaps with both the third and fourth doses of DTP/DTaP vaccine. Providers may unwittingly administer an extra polio dose with the fourth dose of DTP/DTaP because they are accustomed to administering these 2 vaccines together. Second, the predominant oral formulation administered to these children is easier to give than a shot and is relatively inexpensive. As recommendations for the increasing use of inactivated poliovirus vaccine[25] are adopted over time, the percentage of children extraimmunized for poliovirus may decrease. This trend should continue to be monitored.

Other factors that might explain the differences in extraimmunization by vaccine type include the number of recommended doses, the age ranges for which the vaccine is recommended, the complexity of the schedule, whether changes have been made in the schedule, how long the vaccine has been on the recommended schedule, and the number of types of vaccine available, including combinations, and whether they follow the same or different schedules. Increased complexity, changes, and multiple choices may lead to confusion and increase the chance of extra doses. More research is warranted to elucidate the impact of these factors, to find other explanatory factors, and then to identify strategies for reducing extraimmunization. In the meantime, vaccine manufacturers and authoritative bodies should consider these factors and their potential impact on extraimmunization when developing new vaccines and making changes in the recommended schedule.

While we are confident in our estimates of the extent of and costs attributable to extraimmunization, some potential limitations to our study should be considered. If our methods for resolving duplicate entries were inadequate when creating composite immunization histories, the extent and cost of extraimmunization might be overestimated. However, because most children have only 1 provider, the potential impact of this limitation is small. Extraimmunization may be slightly overestimated for hepatitis B vaccine and underestimated for Hib vaccine because multiple products and vaccine schedules are acceptable.[26,27]

Excluding children without provider information may limit the generalizability of this study, since those children had significantly different demographic characteristics from children with provider information and, by parent report, were less likely to be up-to-date with the 4:3:1 vaccination series. We also do not have information on the characteristics of children who were both underimmunized and extraimmunized. In part because estimates were weighted to be representative of all US children aged 19 to 35 months, these limitations should not substantially affect our estimate of extraimmunization.

In our cost calculations we had to make assumptions regarding vaccine type administered, payment source, and "extra" visits. However, we still believe our cost results to be a conservative estimate.

CONCLUSION

For the first time, to our knowledge, the extent of extraimmunization has been estimated on a national scale and found to be substantial and costly. The challenge now will be learning how to reduce extraimmunization without interfering with the more important efforts to combat underimmunization and achieve adequate immunization.

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A creative work of art is, by its very novelty, aggressive; spontaneously aggressive, it strikes out at the public, against the majority; it arouses indignation by its non-conformity, which is, in itself, a form of vindication.

—Eugène Ionesco (1912-1994)